

<b>Substitute for form 1449B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)  Sheet 1 of 3				<b>Complete if Known</b>	
				Application Number	10/600,266
				Filing Date	June 20, 2003
				First Named Inventor	Fumitoshi Asai
				Art Unit	1614
				Examiner Name	Brian S. Kwon
				Attorney Docket Number	13509.105003US

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US 6,693,115	02-17-2004	Asai et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/600,266
				Filing Date	June 20, 2003
				First Named Inventor	Fumitoshi Asai
				Art Unit	1614
				Examiner Name	Brian S. Kwon
Sheet	2	of	3	Attorney Docket Number	13509.105003US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Asai, Fumitoshi et al., "Platelet inhibitory activity and pharmacokinetics of prasugrel (CS-747) a novel thienopyridine P2Y <sub>12</sub> inhibitor: A single ascending dose study in healthy humans," Platelets, vol. 17, no. 4, pp. 209-217, June 2006	
		Chen et al., "Aspirin resistance is associated with a higher incidence of myonecrosis after nonurgent percutaneous coronary intervention despite clopidogrel pretreatment," J Am Coll Cardiol, 43:1122-6, 1125 (2004)	
		FDA Cardiovascular and Renal Drugs Advisory Committee, Slide Presentation and Transcript of Meeting, February 3, 2009, available at << <a href="http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm125999.htm">http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm125999.htm</a> >>	
		Goodman and Gilman, The Pharmacological Basis of Therapeutics, Fifth Edition, p. 25-26, 1975	
		Herbert, J.M. et al., "The anti-aggregating and antithrombotic activity of ticlopidine is potentiated by aspirin in the rat," Thromb. Haemost., vol. 76, pp. 94-98, 1996	
		Herbert, J.M. et al., "The anti-aggregating and antithrombotic activity of clopidogrel is potentiated by aspirin in several experimental models in the rabbit," Thromb. Haemost., vol. 80, pp. 512-518, 1998	
		Ikeda, "Preface: Antiplatelet Therapy- An Update," Haemostasis, vol. 30, Suppl. 3, 2000, p. 1	
		Jakubowski, J.A. et al., "A multiple dose study of prasugrel (CS-747), a novel thienopyridine P2Y <sub>12</sub> inhibitor, compared with clopidogrel in healthy humans," British Journal of Clinical Pharmacology, vol. 63, no. 4, pp. 421-430, October 31, 2006	
		Jarvis et al., "Clopidogrel: A Review of its Use in the Prevention of Atherothrombosis," Drugs, 60(2):347-377, August 2000, Abstract	
		Jernberg, Tomas et al., "Prasugrel achieves greater inhibition of platelet aggregation and a lower rate of non-responders compared with clopidogrel in aspirin-treated patients with stable coronary artery disease," European Heart Journal, vol. 27, pp. 1166-1173, 2006	

Substitute for form 1449B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				Application Number	10/600,266
				Filing Date	June 20, 2003
				First Named Inventor	Fumitoshi Asai
				Art Unit	1614
				Examiner Name	Brian S. Kwon
(Use as many sheets as necessary)				Attorney Docket Number	13509.105003US
Sheet	3	of	3		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Lev et al., "Aspirin and Clopidogrel Drug Response in Patients Undergoing Percutaneous Coronary Intervention," Journal of the American College of Cardiology, 47(1):27-33 (2006)	
		Matsushima, Nobuko et al., "Platelet inhibitory activity and pharmacokinetics of prasugrel (CS-747) a novel thienopyridine P2Y12 inhibitor: A multiple-dose study in healthy humans," Platelets, vol. 17, no. 4, pp. 218-226, June 2006	
		PLAVIX® Prescribing Information, "Dosage and Administration," revised May 2009	
		Sacco et al., "Update on Antiplatelet Therapy for Stroke Prevention," Arch. Intern. Med., 160, June 12, 2000, 1579-1582, Abstract	
		Steinhubl, "Antiplatelet Agents in Cardiology: The Choice of Therapy," Ann. Thorac. Surg, 70:S3-8, 2000, presented Jan. 22-23, 1999	
		TICLID® Prescribing Information, revised March 2001	
		Van de Graaff, "Antiplatelet medications and their indications in preventing and treating coronary thrombosis," Annals of Medicine, 32(8), November 2000, p. 561-571, Abstract	
		Van de Graaff et al., "Variable Interindividual Responses to Antiplatelet Therapies- Do They Exist, Can We Measure Them, and Are They Clinically Relevant?" Heart Drug, 1(1):35-43 (2001), available online August 2000	
		Weerakkody, Govinda J. et al., "Comparison of Speed of Onset of Platelet Inhibition After Loading Doses of Clopidogrel Versus Prasugrel in Healthy Volunteers and Correlation With Responder Status," Am J Cardiol, vol. 100, pp. 331-336, 2007	

Examiner Signature	/Brian Yong Kwon/	Date Considered	11/21/2009
-----------------------	-------------------	--------------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**